K121904

SECTION IV

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

MAR 1 1 2013

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Smith & Nephew Gynecology Instrument Tray

Date Prepared: **June 27, 2012**

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road
Andover, MA 01810

B. Company Contact

Janice Haselton
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Janice.haselton@smith-nephew.com

C. Device Name

Trade Name:	Smith & Nephew Gynecology Instrument Tray
Common Name:	Sterilization Tray
Classification Name:	Sterilization Wrap
Class:	2
Product Code:	KCT
Classification Number:	21 CFR §880.6850

D. Predicate Devices

The Smith & Nephew Gynecology Instrument Tray is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device in commercial distribution:

K090562 (cleared March 18, 2009):
ELITE Premium Biceps Tenodesis System

E. Description of Device

The Smith & Nephew Gynecology Instrument Tray is a stainless steel tray provided with instrument holders, internal compartment and a pin mat. The tray is designed to contain and protect reusable surgical instruments during transport, sterilization, and storage and to allow optimal exposure of the tray's contents to sterilant during the sterilization process.

The technological characteristics of the subject tray are identical to the predicate device. The number of instrument holders and pin mats and material of construction are similar to the predicate. The indications for use statement is unchanged from the predicate tray.

Non clinical validation testing was conducted for sterilization and functional strength in order to demonstrate that the subject device is safe and effective, and whose performance meets the requirements of its pre-defined acceptance criteria and intended uses.

F. Intended Use

Indications For Use	The Smith & Nephew instrument tray is intended to contain Smith & Nephew reusable surgical instrumentation for convenient organized storage, sterilization and transport between usages. The instrument tray must be doubled wrapped with an FDA cleared polypropylene sterilization wrap. The instrument wrap is suitable for use in pre-vacuum steam sterilization method. The instrument tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated sterilization wrap in order to maintain sterility of the enclosed devices. Maintenance of sterility is dependent on the sterilization wrap shelf life and not the tray. Users must follow the instructions for use supplied with the sterilization wrap and follow the manufacturer's recommended storage conditions and time frames for shelf life. The maximum number of devices that could be processed in one load is five. The maximum weight load is 8.4lbs.

Validated Sterilization Parameters

Instrument Tray Contents	Max loaded Tray Weight 8.4 lbs.
Device Type	**Dimensions**
Hysteroscope	Length: 334mm Max., Diameter: 8mm Max. Lumen: 3.1mm Min.
Handpiece	Length: 203mm Max., Diameter: 32mm Max. Lumen: 5.1mm Max
Sheath	Length: 230mm Max., Diameter: 9mm Max. Lumen: 4.6mm Min.
Calibration Insert / Obturator	Length: 385mm Max., Diameter: 4.1mm Max.
Diagnostic Sheath	Length: 390mm Max., Diameter: 2.9mm Max. Lumen: 1.9mm Min.

Validated Sterilization Parameters:

Method	Temperature	Exposure Time	Drying Time
Pre-vacuum steam	132° C (270° F)	4 minutes	30 minutes

G. Comparison of Technological Characteristics

The subject Smith & Nephew Gynecology Instrument tray has the same fundamental technological characteristics as the unmodified predicate device. The subject tray is substantially equivalent in design, materials and intended use to the predicate device. There are no significant differences between the proposed and predicate devices that raise new questions of safety or efficacy.

H. Summary Performance Data

Performance testing was conducted in accordance with ANSI/AAMI ST77:2006 *Containment Devices for reusable medical device sterilization.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 11, 2013

Ms. Janice Haselton
Senior Regulatory Affairs Specialist
Smith & Nephew Incorporated, Endoscopy Division
150 Minuteman Road
ANDOVER MA 01810

Re: K121904
Trade/Device Name: Gynecology Instrument Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: February 25, 2013
Received: February 28, 2013

Dear Ms. Haselton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121904

Device Name: Smith & Nephew Gynecology Instrument Tray

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Device model that is the subject of this pre-market notification:

REF	Description
72203004	Gynecology Instrument Tray

Prescription Use _____ AND/OR Over-The-Counter Use
__X___

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie
2013.03.07 15:32:48 -05'00'

Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121904